Remarks

The Office Action mailed 14 December 2004 has been received and reviewed. Claims 1, 20, 26, 28, 47, 50, and 78 having been amended, and no claims having been added or canceled herein, the pending claims are claims 1, 3-28, 30-55, 62-67, 77, and 78. Claims 1, 3-28, and 30-49 having been withdrawn from consideration by the Examiner, the claims currently under consideration are claims 50-55, 62-67, and 77-78.

All the pending independent claims (i.e., claims 1, 20, 26, 28, 47, 50, and 78) have been amended to explicitly recite "solid hydrophilic particles" that are "partially embedded" within a hydrophobic matrix. The amendment is supported by the specification at, for example, page 10, line 14 to page 11, line 19.

Reconsideration and withdrawal of the rejections are respectfully requested.

Information Disclosure Statement

Applicants submitted an Information Disclosure Statement on 1 March 2004, but have not yet received an initialed 1449 form indicating that the cited documents have been considered by the Examiner. Courtesy copies of the Information Disclosure Statement, 1449 form, and a copy of the return receipt postcard (marked as Exhibit A, B, and C, respectively) are included for the Examiner's convenience. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Provisional Obviousness-Type Double Patenting Rejection

Claims 50-53 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-58 of co-pending Application No. 10/417,609 in view of Dusterhoft et al. (U.S. Patent No. 6,451,260). Claims 50-

53 were also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-53 of co-pending Application No. 10/027,222 in view of Dusterhoft et al. (U.S. Patent No. 6,451,260).

Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response. In the event that the provisional obviousness-type double patenting rejections are the only rejections remaining in the present application, the Examiner is respectfully requested to withdraw the provisional obviousness-type double patenting rejection and allow the present application to issue as a patent pursuant to M.P.E.P. §822.01.

Rejection under 35 U.S.C. §103

The Examiner rejected under 35 U.S.C. §103(a) claims 50-52, 64-65, and 77-78 as being unpatentable over Nelson et al. (U.S. Patent No. 6,344,326) in view of Dusterhoft et al. (U.S. Patent No. 6,451,260); claim 53 as being unpatentable over Nelson et al. and Dusterhoft et al. as applied above, and further in view of Mian et al. (U.S. Patent No. 6,319,469); claims 54-55 and 66-67 as being unpatentable over Nelson et al. and Dusterhoft et al. as applied above, and further in view of Chisolm et al. (U.S. Patent No. 4,399,009); and claims 62-63 as being unpatentable over Nelson et al. and Dusterhoft et al., and further in view of Kellogg et al. (U.S. Patent No. 6,632,399). Applicants respectfully traverse the rejections.

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974), M.P.E.P. §2143.03. Language must be given plain and ordinary meaning. "Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say." M.P.E.P. §2111.01.Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

As admitted by the Examiner, "Nelson does not teach a solid phase extraction material comprised of a hydrophilic solid support partially embedded within a hydrophobic matrix" (page 6 of the Office Action mailed 14 December 2004). Instead, the Examiner is relying on Dusterhoft et al. to provide that which is missing from Nelson et al.

Independent claims 50 and 78 have been amended to make it abundantly clear that they refer to ***solid hydrophilic particles*** that are ***partially embedded*** within a hydrophobic matrix. The Examiner noted that a "particle" may be defined as a "minute quantity or fragment" or as "a relative small or the smallest discrete portion or amount of something" (page 6, lines 7-9 of the Office Action mailed 27 July 2004). However, Applicants note that the claims recite ***solid*** hydrophilic particles. Thus, according to the definitions offered by the Examiner, the smallest discrete portion of a ***solid*** hydrophilic particle would still be a solid. Moreover, Applicants respectfully submit that one of skill in the art, in view of the specification as a whole (e.g., including the claims) would recognize that a solid particle is a solid that has measurable properties including, for example, a particle size (*see, for example*, EXHIBIT D for a discussion of particles and particle size; *see, also*, claims 62-63 for average particle sizes of preferred embodiments); surface properties (e.g., hydrophilic); and capable of being partially embedded within a hydrophobic matrix.

An unresolved issue is whether Dusterhoft et al. teach ***solid hydrophilic particles*** that are ***partially embedded*** within a hydrophobic matrix. On page 8, the first paragraph of the Office Action mailed 14 December 2004, the Examiner pointed to the paragraph at column 11, lines 11-40 (referred to by the Examiner and hereinafter as "paragraph 76") or, in the alternative, the paragraph at column 11, line 41 to column 12, line 15 (referred to by the Examiner and hereinafter as "paragraph 77") of Dusterhoft et al. as providing that which is missing from Nelson et al. Applicants respectfully disagree.

PARAGRAPH 76 OF DUSTERHOFT ET AL. DOES NOT DISCLOSE SOLID HYDROPHILIC PARTICLES

Paragraph 76 of Dusterhoft et al. recites the following:

> Without intending to be bound to theory it is believed that in generating the microporous element according to the present invention the following mechanisms are involved: When the nonsolvent diffuses into the layer of resin solution, the solubility of the resin is gradually decreased. As the limit of solubility is reached the resin begins to precipitate from the solution at individual points. The precipitation of the resin proceeds at the points of initial precipitation. Ultimately, the solvent/nonsolvent is enclosed in large interconnecting enclaves in a solid matrix of resin. The interconnecting enclaves form the liquid-permeable channels of the final microporous element. If a synthetic resin is used which comprises both hydrophilic and hydrophobic segments, the hydrophobic segments will be forced towards each other and brought into contact with each other as the concentration of nonsolvent in the resin solution increases. There will be interactions between the hydrophobic segments of neighboring molecule chains, which result in the formation of a crystalline hydrophobic backbone of the precipitated resin. The hydrophilic segments will be oriented towards the enclaves filled with solvent/nonsolvent. Accordingly, a microporous element is obtained where the liquid-permeable channels are predominantly hydrophilic. This provides the benefit of biocompatibility. The term "biocompatibility" means that the three-dimensional structure of biopolymers, for example proteins, peptides, nucleic acids, oligonucleotides, polysaccharides or derivatives thereof, is maintained. The interphase forces are less destructive when the polymer surface is rich in hydroxyl, amide or ether groups.

Notably, paragraph 76 lacks any disclosure of particles, much less a disclosure of ***solid hydrophilic particles*** that are ***partially embedded*** within a hydrophobic matrix.

Nonetheless, in referring to the above recited "synthetic resin . . . which comprises both hydrophilic and hydrophobic segments" (column 11, lines 22-24), the Examiner asserted that "the cited teachings of the hydrophilic segments provide a teaching of hydrophilic solid particles" (page 6, lines 5-7 of the Office Action mailed 27 July 2004). Applicants earnestly disagree.

As discussed herein above, the present claims recite "solid hydrophilic particles." Applicants respectfully submit that one of skill in the art would not consider a hydrophilic segment of a polymer to be a solid hydrophilic particle. Applicants respectfully submit that one of skill in the art would not refer to a portion of a molecule (e.g., a segment of a polymer) as a solid, much less a solid particle. Moreover, the Examiner has provided no evidence to support his assertion that a segment of a polymer is a solid particle.

Further, to the extent that the Examiner is referring to the whole of the synthetic resin, that includes both hydrophilic and hydrophobic segments, as being a "particle," Applicants respectfully disagree. Paragraph 76 of Dusterhoft et al. refers to a "solid matrix of resin," but makes no reference to particles of resin. Applicants respectfully submit that one of skill in the art would recognize that a matrix is "[a] surrounding substance within which something is contained or embedded" (*see, for example*, EXHIBIT E), and not a solid particle as claimed by Applicants.

Thus, Applicants respectfully submit that Paragraph 76 of Dusterhoft et al. fails to disclose solid hydrophilic particles.

PARAGRAPH 77 OF DUSTERHOFT ET AL. DOES NOT DISCLOSE PARTICLES PARTIALLY EMBEDDED WITHIN A HYDROPHOBIC MATRIX

Paragraph 77 of Dusterhoft et al. recites the following:

> In order to modify the adsorptive properties of the microporous element, the solution of the synthetic resin may further comprise solid microparticles. The micro particles may be composed of silicon dioxide, silica gel, aluminum oxide, titan dioxide, zirconium oxide, glass, carbon or graphite. Also, the particles can be composed of inorganic material, such as calcium phosphate, zinc polyphosphate or the like. Another type of granular microparticles consists of an inorganic core such as microporous silica gel with a microlayer of organic polymer. The pores and the surface of the grain may be modified in a way, that macromolecules are restricted from penetrating into the pores ("Restricted access material"). Also, the micro particles may consist of organic material such as a powder of cured resin, or highly crosslinked polysaccharides, as are available under the sephadex

> tradename, however care has to be taken in selecting an organic material in that it must not be soluble in the solvent used. The particles can be non-porous or porous, but preferably are porous with a preferred pore size in the range of 1 nm to 500 nm. Generally, the particles have a size from 5 nm to 80 mm, in particular from 0.5 mm to 30 mm, however porous microparticles preferably have a size of 1 mm or more, whereas nonporous microparticles preferably have a size of 1 mm or less. The microparticles can be pretreated, e.g., derivatized, such that the adsorbent properties thereof meet specific requirements. Any kind of commercially available adsorbent particles as used for solid phase extraction or chromatography, such as affinity chromatography with proteins, antibodies, peptides, carbohydrates, nucleic acids, or for ion exchange chromatography, immuno chromatography, hydrophobic interaction chromatography, chelating chromatography and reversed phase chromatography are useful. Materials suited for high performance liquid chromatography are especially useful. For example proteins, such as specific antibodies, lectins, avidin, receptor-proteins, enzymes, synthetic peptides, nucleic acids or oligonucleotides may be attached to the microparticles, either covalently or via linkers. The adsorbent particles have a granular shape, for example spherical. The microparticles may be used, e.g., in an amount of up to 50 mg, preferably 100 ng to 20 mg, per filter element.

Thus, paragraph 77 of Dusterhoft et al. clearly discloses solid microparticles. However, paragraph 77 fails to specifically disclose that such solid microparticles are ***hydrophilic***. Furthermore, paragraph 77 fails to disclose that such solid microparticles are ***partially embedded*** (i.e., not totally embedded) within a matrix.

Moreover, the Examiner noted that "[t]he microporous elements of Dusterhoft are best shown in Figures 1-5" (page 6, line 12 of the Office Action mailed 14 December 2004). Although Figures 1-5 clearly show particles totally embedded within a matrix, Applicants respectfully submit that the Examiner has failed to specifically point to any disclosure in Dusterhoft et al. of solid hydrophilic particles ***partially embedded*** within a matrix.

Finally, paragraph 77 of Dusterhoft et al. recites that "the solution of the synthetic resin may further comprise solid microparticles" (column 11, lines 42-43). Thus, Dusterhoft et al. contemplates embedding the solid microparticles disclosed in paragraph 77 in the synthetic resin disclosed in paragraph 76. As discussed herein above, the synthetic resin has a hydrophilic

character, and thus, does not form a hydrophobic matrix, i.e., "a microporous element is obtained where the liquid-permeable channels are predominantly hydrophilic" (column 11, lines 32-33 of Dusterhoft et al.).

Thus, Applicants respectfully submit that all the claim language is neither taught nor suggested by the cited art, and that the Examiner has failed to establish a *prima facie* case of obviousness. Based on the remarks presented herein, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §103.

Request for Rejoinder

Claims 1, 3-28, and 30-49 recite methods of using a device as recited, for example, in claims 50 and/or 78. Specifically, independent claims 1, 20, 26, 28, and 47 recite language from independent claims 50 and 78. Upon an indication of claim 50 or 78 being allowable, Applicants respectfully request that the method claims (e.g., claims 1, 3-28, and 30-49) also be examined and passed on to allowance pursuant to M.P.E.P. §821.04. *See, for example, In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fec. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
PARTHASARATHY et al.

By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228

March 11, 2005
Date

By: _____
Loren D. Albin
Reg. No. 37,763
Direct Dial (612) 305-1225

CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 11th day of March, 2005, at 11:04 a.m. (Central Time).

By: _____
Name: Rachel Coglianese-Gebhardt